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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/692,730

10/27/2003

Jian Ni

PF293D2

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22195 7590 05/22/2007  
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EXAMINER

JIANG, DONG

ART UNIT

PAPER NUMBER

1646

MAIL DATE

DELIVERY MODE

05/22/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                               |                           |  |
|------------------------------|-------------------------------|---------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>10/692,730 | Applicant(s)<br>NI ET AL. |  |
|                              | Examiner<br>Dong Jiang        | Art Unit<br>1646          |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-90 is/are pending in the application.
- 4a) Of the above claim(s) 17,18,42,59,60 and 84 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 27-41,69-83 and 85-90 is/are allowed.
- 6) ☒ Claim(s) 1-3,7,9,11-14,19-21,26,43-45,49,51,53-56,61-63 and 68 is/are rejected.
- 7) ☒ Claim(s) 4-6,8,10,15,16,22-25,46-48,50,52,57,58 and 64-67 is/are objected to.
- 8) ☒ Claim(s) 1-90 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED OFFICE ACTION

Applicant's amendment filed on 01 February 2007 is acknowledged and entered. Following the amendment, claim 85 is amended.

Currently, claims 1-90 are pending, and claims 1-16, 19-41, 43-58, 61-83 and 85-90 are under consideration.

#### **Rejections Over Prior Art:**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7, 9, 13, 14, 19-21, 26, 43-45, 49, 51, 55, 56, 61-63 and 68 are rejected under 35 U.S.C. 102(b) as being anticipated by Gayle et al. (US5,576,191), as evidenced by Benjamini et al. (Immunity, A Short Course, 2<sup>nd</sup> ed., 1992, page 40).

Gayle discloses a cytokine ligand that binds ST2 receptor, wherein the amino acid sequence of the ST2 ligand, SEQ ID NO:4, comprises the amino acids 175-186 of the present SEQ ID NO:2 (see attached sequence alignment). Additionally, Gayle teaches the antibodies to the ST2 ligand, which can be obtained by immunizing mice with the ligand polypeptide, and screening serum samples of the immunized animals by dot blot or ELISA (column 23, lines 3-12). Therefore, the reference anticipates the claims. Note, although the cited shared sequence comprised only 12 amino acids, the art has established that the size of an epitope is approximately equivalent to 5 to 7 amino acids (Immunity, A Short Course, Benjamini et al., 2<sup>nd</sup> ed., 1992, page 40).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11, 12, 53 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Gayle et al. (US5,576,191), as evidenced by Benjamini et al. (Immunity, A Short Course, 2<sup>nd</sup> ed., 1992, page 40), as applied to claims 1-3, 7, 9, 13, 14, 19-21, 26, 43-45, 49, 51, 55, 56, 61-63 and 68 above, and further in view of Hermanus et al., US 3,654,090.

The teachings of Gayle are reviewed above. The primary reference does not teach that the antibody is labeled.

Hermanus teaches a method of making enzyme-labeled antibodies or antigens for the determination of antibodies or antigens. Additionally, the reference teaches that enzymes can be detected in very small amounts; the method avoids the use of radio-isotope techniques, does not requires a radio-isotope equipment, and can be performed in every laboratory; and measuring enzyme activity is usually less time-consuming than counting radio activity (the paragraph bridging columns 1 and 2).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to enzyme-label the antibody taught by Gayle using the method taught by Hermanus. The person of ordinary skill in the art would have been motivated to do so for detecting the presence of the ST2 ligand polypeptide because of the advantages suggested by Hermanus, and reasonably would have expected success because Hermanus has demonstrated that such enzyme-labeled antibody can be used for detection of the specific antigen (Example 5).

**Conclusion:**

Claims 27-41 and 69-83 and 85-90 are allowable.

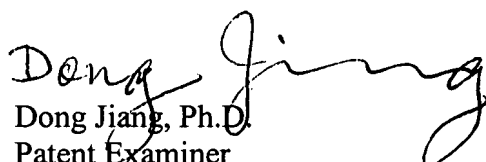
Claims 4-6, 8, 10, 15, 16, 22-25, 46-48, 50, 52, 57, 58 and 64-67 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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**Advisory Information:**

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

  
Dong Jiang, Ph.D.  
Patent Examiner  
AU1646  
4/12/06